

This listing of claims replaces all prior versions and listings of claims in this application.

**LISTING OF CLAIMS:**

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Claims 1-12 (Canceled)

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Claim 13 (Original): A method for preparing a subcutaneously administrable biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form a subcutaneously administrable supramolecular complex,

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous

delivery of said biologically active agent.

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Claim 14 (Original): A method as defined in claim 13, wherein said intermediate state has G ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 15 (Original): A method as defined in claim 13, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 16 (Previously Presented): A method as defined in claim 15, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial natriuretic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 17 (Original): A method as defined in claim 13, wherein said perturbant comprises a proteinoid.

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*part*

Claim 18 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 19 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 20 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 21 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 22 (Original): A method as defined in claim 13, wherein said perturbant comprises a carboxylic acid having the formula



wherein R is C<sub>1</sub> to C<sub>24</sub> alkyl, C<sub>2</sub> to C<sub>24</sub> alkenyl, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, phenyl, naphthyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)phenyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)phenyl, (C<sub>1</sub> to C<sub>10</sub> alkyl) naphthyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)naphthyl, phenyl(C<sub>1</sub> to C<sub>10</sub> alkyl), phenyl(C<sub>2</sub> to C<sub>10</sub> alkenyl), naphthyl(C<sub>1</sub> to C<sub>10</sub> alkyl) and naphthyl(C<sub>2</sub> to C<sub>10</sub> alkenyl);  
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R being optionally substituted with C<sub>1</sub> to C<sub>10</sub> alkyl, C<sub>2</sub> to C<sub>10</sub> alkenyl, C<sub>1</sub> to C<sub>4</sub> alkoxy, -OH, -SH, -CO<sub>2</sub>R<sup>1</sup>, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C<sub>1</sub> to C<sub>10</sub> alkyl)aryl, aryl(C<sub>1</sub> to C<sub>10</sub>)alkyl, or any combination thereof;

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cont R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R<sup>1</sup> is hydrogen, C<sub>1</sub> to C<sub>4</sub> alkyl or C<sub>2</sub> to C<sub>4</sub> alkenyl; or  
a salt thereof.

Claim 23 (Original): A subcutaneous delivery composition comprising a supramolecular complex comprising:

(a) a biologically active agent in an intermediate conformational state non-covalently complexed with  
(b) a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;  
wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent.

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Claim 24 (Original): A composition as defined in claim 23, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 25 (Previously Presented): A composition as defined in claim 24, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial natriuretic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 26 (Original): A composition as defined in claim 23, wherein said perturbant comprises a proteinoid.

Claim 27 (Original): A composition as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

*Impurity*

Claim 28 (Original): A method as defined in claim 46, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a {M:\1946\1A483\00056406.DOC [REDACTED]}

sulfonated poly amino acid.

Claim 29 (Original): A method as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

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*cont*  
Claim 30 (Original): A method as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 31 (Original): A method as defined in claim 23, wherein said perturbant comprises a carboxylic acid having the formula



wherein R is C<sub>1</sub> to C<sub>24</sub> alkyl, C<sub>2</sub> to C<sub>24</sub> alkenyl, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, phenyl, naphthyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)phenyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)phenyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)naphthyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)naphthyl, phenyl(C<sub>1</sub> to C<sub>10</sub> alkyl), phenyl(C<sub>2</sub> to C<sub>10</sub> alkenyl), naphthyl(C<sub>1</sub> to C<sub>10</sub> alkyl) and naphthyl(C<sub>2</sub> to C<sub>10</sub> alkenyl);

R being optionally substituted with C<sub>1</sub> to C<sub>10</sub> alkyl, C<sub>2</sub> to C<sub>10</sub> alkenyl, C<sub>1</sub> to C<sub>4</sub> alkoxy, -OH, -SH, -CO<sub>2</sub>R<sup>1</sup>, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C<sub>1</sub> to C<sub>10</sub> alkyl)aryl, aryl(C<sub>1</sub> to C<sub>10</sub>)alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination  
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thereof; and

R<sup>1</sup> is hydrogen, C<sub>1</sub> to C<sub>4</sub> alkyl or C<sub>2</sub> to C<sub>4</sub> alkenyl; or  
a salt thereof.

Claim 32 (Original): A dosage unit form comprising:

(A) a composition as defined in claim 23; and

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*cont*

(B) (a) an excipient,  
(b) a diluent,  
(c) a disintegrant,  
(d) a lubricant,  
(e) a plasticizer,  
(f) a colorant,  
(g) a dosing vehicle, or  
(h) any combination thereof.

Claim 33 (Original): A method for preparing an agent which is capable of being administered by the subcutaneous route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a subcutaneously administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

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*Cont*  
said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex.

Claim 34 (Original): A method as defined in claim 33, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 35 (Original): A method for preparing an agent which is capable of being administered by the subcutaneous route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is

reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

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cont*  
(c) preparing a mimetic of said intermediate state.

Claim 36 (Original): A method as defined in claim 35, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claim 37 (Currently Amended): A subcutaneous delivery composition comprising a mimetic, the mimetic being a mimetic of the a subcutaneous delivery composition prepared by the method of claim 13.

Claims 38-49 (Canceled)

Claim 50 (Original): A method for preparing a sublingually administrable biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally {M:\1946\1A483\00056406.DOC [REDACTED] }

between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex,

    said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

    said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

    said biologically active agent not forming a microsphere with said perturbant;  
    wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent.

Claim 51 (Original): A method as defined in claim 50, wherein said intermediate state has  $G$  ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 52 (Original): A method as defined in claim 50, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 53 (Previously Presented): A method as defined in claim 52,  
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wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial natriuretic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

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Claim 54 (Original): A method as defined in claim 50, wherein said perturbant comprises a proteinoid.

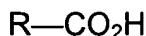
Claim 55 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 56 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 57 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 58 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 59 (Original): A method as defined in claim 50, wherein said perturbant comprises a carboxylic acid having the formula



wherein R is C<sub>1</sub> to C<sub>24</sub> alkyl, C<sub>2</sub> to C<sub>24</sub> alkenyl, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, phenyl, naphthyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)phenyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)phenyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)naphthyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)naphthyl, phenyl(C<sub>1</sub> to C<sub>10</sub> alkyl), phenyl(C<sub>2</sub> to C<sub>10</sub> alkenyl), naphthyl(C<sub>1</sub> to C<sub>10</sub> alkyl) and naphthyl(C<sub>2</sub> to C<sub>10</sub> alkenyl);

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R being optionally substituted with C<sub>1</sub> to C<sub>10</sub> alkyl, C<sub>2</sub> to C<sub>10</sub> alkenyl, C<sub>1</sub> to C<sub>4</sub> alkoxy, -OH, -SH, -CO<sub>2</sub>R<sup>1</sup>, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C<sub>1</sub> to C<sub>10</sub> alkyl)aryl, aryl(C<sub>1</sub> to C<sub>10</sub>)alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R<sup>1</sup> is hydrogen, C<sub>1</sub> to C<sub>4</sub> alkyl or C<sub>2</sub> to C<sub>4</sub> alkenyl; or  
a salt thereof.

Claim 60 (Original): A sublingual delivery composition comprising a  
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supramolecular complex comprising:

- (a) a biologically active agent in an intermediate conformational state non-covalently complexed with
  - (b) a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent.

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Claim 61 (Original): A composition as defined in claim 60, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 62 (Previously Presented): A composition as defined in claim 61, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial natriuretic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin,

desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 63 (Original): A composition as defined in claim 60, wherein said perturbant comprises a proteinoid.

Claim 64 (Original): A composition as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

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cont.*  
Claim 65 (Original): A method as defined in claim 60, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 66 (Original): A method as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 67 (Original): A method as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 68 (Original): A method as defined in claim 60, wherein said  
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perturbant comprises a carboxylic acid having the formula



wherein R is C<sub>1</sub> to C<sub>24</sub> alkyl, C<sub>2</sub> to C<sub>24</sub> alkenyl, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, phenyl, naphthyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)phenyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)phenyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)naphthyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)naphthyl, phenyl(C<sub>1</sub> to C<sub>10</sub> alkyl), phenyl(C<sub>2</sub> to C<sub>10</sub> alkenyl), naphthyl(C<sub>1</sub> to C<sub>10</sub> alkyl) and naphthyl(C<sub>2</sub> to C<sub>10</sub> alkenyl);

R being optionally substituted with C<sub>1</sub> to C<sub>10</sub> alkyl, C<sub>2</sub> to C<sub>10</sub> alkenyl, C<sub>1</sub> to C<sub>4</sub> alkoxy, -OH, -SH, -CO<sub>2</sub>R<sup>1</sup>, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C<sub>1</sub> to C<sub>10</sub> alkyl)aryl, aryl(C<sub>1</sub> to C<sub>10</sub>)alkyl, or any combination thereof;

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R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R<sup>1</sup> is hydrogen, C<sub>1</sub> to C<sub>4</sub> alkyl or C<sub>2</sub> to C<sub>4</sub> alkenyl; or a salt thereof.

Claim 69 (Original): A dosage unit form comprising:

- (A) a composition as defined in claim 60; and
- (B) (a) an excipient,
  - (b) a diluent,
  - (c) a disintegrant,
  - (d) a lubricant,

- (e) a plasticizer,
- (f) a colorant,
- (g) a dosing vehicle, or
- (h) any combination thereof.

Claim 70 (Original): A method for preparing an agent which is capable of being administered by the sublingual route to a subject in need of said agent, said method comprising:

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- (a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;
- (b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex,
  - said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophobic moiety,
  - said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and
  - said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for sublingual delivery of

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said biologically active agent; and

- (c) preparing a mimetic of said supramolecular complex.

Claim 71 (Original): A method as defined in claim 70, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 72 (Original): A method for preparing an agent which is capable of being administered by the sublingual route to a subject in need of said agent, said method comprising:

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cont'd*

- (a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

- (b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent; and

- (c) preparing a mimetic of said intermediate state.

Claim 73 (Original): A method as defined in claim 72, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

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Claim 74 (Currently Amended): An oral A sublingual delivery composition comprising a mimetic, the mimetic being a mimetic of the oral a sublingual delivery composition prepared by the method of claim 50.

Claims 75-86 (Canceled)

Claim 87 (Original): A method for preparing an intranasally administrable biologically active agent, said method comprising:

- (a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and
- (b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex,  
said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,  
said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and  
said biologically active agent not forming a microsphere with said perturbant;  
wherein said perturbant is in an amount effective for intranasal delivery of said

biologically active agent.

Claim 88 (Original): A method as defined in claim 87, wherein said intermediate state has G ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 89 (Original): A method as defined in claim 87, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

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*cont'd*

Claim 90 (Previously Presented): A method as defined in claim 89, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial natriuretic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 91 (Original): A method as defined in claim 87, wherein said perturbant comprises a proteinoid.

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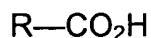
Claim 92 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 93 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 94 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 95 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 96 (Original): A method as defined in claim 87, wherein said perturbant comprises a carboxylic acid having the formula



wherein R is C<sub>1</sub> to C<sub>24</sub> alkyl, C<sub>2</sub> to C<sub>24</sub> alkenyl, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, phenyl, naphthyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)phenyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)phenyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)naphthyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)naphthyl, phenyl(C<sub>1</sub> to C<sub>10</sub> alkyl), phenyl(C<sub>2</sub> to C<sub>10</sub> alkenyl), naphthyl(C<sub>1</sub> to C<sub>10</sub> alkyl) and naphthyl(C<sub>2</sub> to C<sub>10</sub> alkenyl);  
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R being optionally substituted with C<sub>1</sub> to C<sub>10</sub> alkyl, C<sub>2</sub> to C<sub>10</sub> alkenyl, C<sub>1</sub> to C<sub>4</sub> alkoxy, -OH, -SH, -CO<sub>2</sub>R<sup>1</sup>, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C<sub>1</sub> to C<sub>10</sub> alkyl)aryl, aryl(C<sub>1</sub> to C<sub>10</sub>)alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R<sup>1</sup> is hydrogen, C<sub>1</sub> to C<sub>4</sub> alkyl or C<sub>2</sub> to C<sub>4</sub> alkenyl; or  
a salt thereof.

*B1  
cont R*  
Claim 97 (Original): An intranasal delivery composition comprising a supramolecular complex comprising:

(a) a biologically active agent in an intermediate conformational state non-covalently complexed with

(b) a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent.

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*cont.*

Claim 98 (Original): A composition as defined in claim 97, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 99 (Previously Presented): A composition as defined in claim 98, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial natriuretic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 100 (Original): A composition as defined in claim 97, wherein said perturbant comprises a proteinoid.

Claim 101 (Original): A composition as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

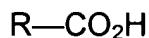
Claim 102 (Original): A method as defined in claim 97, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

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Claim 103 (Original): A method as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 104 (Original): A method as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 105 (Original): A method as defined in claim 97, wherein said perturbant comprises a carboxylic acid having the formula



wherein R is C<sub>1</sub> to C<sub>24</sub> alkyl, C<sub>2</sub> to C<sub>24</sub> alkenyl, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, phenyl, naphthyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)phenyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)phenyl, (C<sub>1</sub> to C<sub>10</sub> alkyl)naphthyl, (C<sub>2</sub> to C<sub>10</sub> alkenyl)naphthyl, phenyl(C<sub>1</sub> to C<sub>10</sub> alkyl), phenyl(C<sub>2</sub> to C<sub>10</sub> alkenyl), naphthyl(C<sub>1</sub> to C<sub>10</sub> alkyl) and naphthyl(C<sub>2</sub> to C<sub>10</sub> alkenyl);

R being optionally substituted with C<sub>1</sub> to C<sub>10</sub> alkyl, C<sub>2</sub> to C<sub>10</sub> alkenyl, C<sub>1</sub> to C<sub>4</sub> alkoxy, -OH, -SH, -CO<sub>2</sub>R<sup>1</sup>, C<sub>3</sub> to C<sub>10</sub> cycloalkyl, C<sub>3</sub> to C<sub>10</sub> cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C<sub>1</sub> to C<sub>10</sub> alkyl)aryl, aryl(C<sub>1</sub> to C<sub>10</sub>)alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R<sup>1</sup> is hydrogen, C<sub>1</sub> to C<sub>4</sub> alkyl or C<sub>2</sub> to C<sub>4</sub> alkenyl; or  
a salt thereof.

Claim 106 (Original): A dosage unit form comprising:

- (A) a composition as defined in claim 97; and
- (B) (a) an excipient,
  - (b) a diluent,
  - (c) a disintegrant,
  - (d) a lubricant,
  - (e) a plasticizer,
  - (f) a colorant,
  - (g) a dosing vehicle, or
  - (h) any combination thereof.

*B  
cont'*

Claim 107 (Original): A method for preparing an agent which is capable of being administered by the intranasal route to a subject in need of said agent, said method comprising:

- (a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;
- (b) exposing said biologically active agent to a complexing perturbant to

reversibly transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex,

    said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophobic moiety,

    said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

    said biologically active agent not forming a microsphere with said perturbant;

    wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex.

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cont.*  
Claim 108 (Original): A method as defined in claim 107, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 109 (Original): A method for preparing an agent which is capable of being administered by the intranasal route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state.

Claim 110 (Original): A method as defined in claim 109, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

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Claim 111 (Original): An oral intranasal delivery composition comprising a mimetic, the mimetic being a mimetic of the oral an intranasal delivery composition prepared by the method of claim 87.

Claim 112 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is human growth hormone.

Claim 113 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 114 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is insulin.

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*cont'd.*

Claim 115 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is heparin.

Claim 116 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is low molecular weight heparin.

Claim 117 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is calcitonin.

Claim 118 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is cromolyn sodium.

Claim 119 (Currently Amended): The method of claim 55 128, wherein the biologically active agent is an antimicrobial.

Claim 120 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is human growth hormone.

Claim 121 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 122 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is insulin.

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*cont.*

Claim 123 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is heparin.

Claim 124 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is low molecular weight heparin.

Claim 125 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is calcitonin.

Claim 126 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is cromolyn sodium.

Claim 127 (Currently Amended): The composition of claim 64 129, wherein the biologically active agent is an antimicrobial.

Claim 128 (New): A method as defined in claim 55, wherein said perturbant is an acylated amino acid.

Claim 129 (New): A composition as defined in claim 64, wherein said perturbant is an acylated amino acid.

Claim 130 (New): A method as defined in claim 128, wherein the biologically active agent is a peptide.

Claim 131 (New): A method as defined in claim 130, wherein the biologically active agent is an interferon.

Claim 132 (New): A method as defined in claim 130, wherein the biologically active agent is erythropoietin.

Claim 133 (New): A method as defined in claim 130, wherein the biologically active agent is an antigen.

Claim 134 (New): A composition as defined in claim 129, wherein the biologically active agent is a peptide.

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cont

Claim 135 (New): A composition as defined in claim 134, wherein the biologically active agent is an interferon.

Claim 136 (New): A composition as defined in claim 134, wherein the biologically active agent is erythropoietin.

Claim 137 (New): A composition as defined in claim 134, wherein the biologically active agent is an antigen.

Claim 138 (New): A method as defined in claim 18, wherein said perturbant is an acylated amino acid.

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*cont'd'*

Claim 139 (New): The method of claim 138, wherein the biologically active agent is human growth hormone.

Claim 140 (New): The method of claim 138, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 141 (New): The method of claim 138, wherein the biologically active agent is insulin.

Claim 142 (New): The method of claim 138, wherein the biologically active agent is heparin.

Claim 143 (New): The method of claim 138, wherein the biologically active agent is low molecular weight heparin.

Claim 144 (New): The method of claim 138, wherein the biologically active agent is calcitonin.

Claim 145 (New): The method of claim 138, wherein the biologically active agent is cromolyn sodium.

Claim 146 (New): The method of claim 138, wherein the biologically active agent is an antimicrobial.

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Claim 147 (New): A method as defined in claim 138, wherein the biologically active agent is a peptide.

Claim 148 (New): A method as defined in claim 147, wherein the biologically active agent is an interferon.

Claim 149 (New): A method as defined in claim 147, wherein the biologically active agent is erythropoietin.

Claim 150 (New): A method as defined in claim 147, wherein the biologically active agent is an antigen.

*cont.*  
Claim 151 (New): A composition as defined in claim 27, wherein said perturbant is an acylated amino acid.

Claim 152 (New): The composition of claim 151, wherein the biologically active agent is human growth hormone.

Claim 153 (New): The composition of claim 151, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 154 (New): The composition of claim 151, wherein the biologically active agent is insulin.

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*cont.*

Claim 155 (New): The composition of claim 151, wherein the biologically active agent is heparin.

Claim 156 (New): The composition of claim 151, wherein the biologically active agent is low molecular weight heparin.

Claim 157 (New): The composition of claim 151, wherein the biologically active agent is calcitonin.

Claim 158 (New): The composition of claim 151, wherein the biologically active agent is cromolyn sodium.

Claim 159 (New): The composition of claim 151, wherein the biologically active agent is an antimicrobial.

Claim 160 (New): A composition as defined in claim 151, wherein the biologically active agent is a peptide.

Claim 161 (New): A composition as defined in claim 160, wherein the biologically active agent is an interferon.

Claim 162 (New): A composition as defined in claim 160, wherein the biologically active agent is erythropoietin.

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*cont.*

Claim 163 (New): A composition as defined in claim 160, wherein the biologically active agent is an antigen.

Claim 164 (New): A method as defined in claim 92, wherein said perturbant is an acylated amino acid.

Claim 165 (New): The method of claim 164, wherein the biologically active agent is human growth hormone.

Claim 166 (New): The method of claim 164, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 167 (New): The method of claim 164, wherein the biologically active agent is insulin.

Claim 168 (New): The method of claim 164, wherein the biologically active agent is heparin.

Claim 169 (New): The method of claim 164, wherein the biologically active agent is low molecular weight heparin.

Claim 170 (New): The method of claim 164, wherein the biologically active agent is calcitonin.

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Claim 171 (New): The method of claim 164, wherein the biologically active agent is cromolyn sodium.

Claim 172 (New): The method of claim 164, wherein the biologically active agent is an antimicrobial.

Claim 173 (New): A method as defined in claim 164, wherein the biologically active agent is a peptide.

Claim 174 (New): A method as defined in claim 173, wherein the biologically active agent is an interferon.

Claim 175 (New): A method as defined in claim 173, wherein the biologically active agent is erythropoietin.

Claim 176 (New): A method as defined in claim 173, wherein the biologically active agent is an antigen.

Claim 177 (New): A composition as defined in claim 101, wherein said perturbant is an acylated amino acid.

Claim 178 (New): The composition of claim 177, wherein the biologically active agent is human growth hormone.

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*cont.*

Claim 179 (New): The composition of claim 177, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 180 (New): The composition of claim 177, wherein the biologically active agent is insulin.

Claim 181 (New): The composition of claim 177, wherein the biologically active agent is heparin.

Claim 182 (New): The composition of claim 177, wherein the biologically active agent is low molecular weight heparin.

Claim 183 (New): The composition of claim 177, wherein the biologically active agent is calcitonin.

Claim 184 (New): The composition of claim 177, wherein the biologically active agent is cromolyn sodium.

Claim 185 (New): The composition of claim 177, wherein the biologically active agent is an antimicrobial.

Claim 186 (New): A composition as defined in claim 177, wherein the biologically active agent is a peptide.

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Claim 187 (New): A composition as defined in claim 186, wherein the biologically active agent is an interferon.

Claim 188 (New): A composition as defined in claim 186, wherein the biologically active agent is erythropoietin.

Claim 189 (New): A composition as defined in claim 186, wherein the biologically active agent is an antigen.

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